

Economic Impact Statement

LSA Document #20-476

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

The Indiana state board of animal health (BOAH) is requesting approval to amend its rules governing dairy products inspection ([345 IAC 8](#)). The primary purpose of the changes is to conform BOAH rules to the 2019 Grade A Pasteurized Milk Ordinance (PMO). BOAH is proposing to update the current incorporation by reference of the 2017 PMO to the 2019 revision. BOAH is also proposing to update the current incorporation by reference of certain Food and Drug Administration (FDA) food standards from April 1, 2016, to April 1, 2020.

A second objective of the proposed rule is to clarify how graded milk, which is defined as all milk produced and processed under a permit issued by the BOAH, is handled in relation to all other milk used for ungraded purposes. The proposed rule adds definitions of "graded milk" and "ungraded milk" to the dairy products rule, which is existing language that is being transferred from a guidance document. It prohibits the storage of ungraded milk in a permitted bulk tank with graded milk. It also clarifies certain procedures for ungraded milk to be harvested using common equipment.

The third objective of the rule is to clarify the construction, operation, and sanitation requirements for manufacturing grade milk plants. In order to comply with federal law, BOAH recently aligned standards for manufacturing grade milk plants with 9 CFR 117, Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (see LSA Document #16-222). In order to align with the new Food Safety Modernization Act (FSMA) regulations at 9 CFR 117, BOAH structured a phase in schedule for the new FSMA regulations. After two years of operating under the FSMA standards, the BOAH has determined that these standards should be supplemented with certain sections of the Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO) and frozen dessert sampling standards.

1. Description of Affected Industry

BOAH currently inspects 792 Grade A dairy farms and 26 Grade A dairy plants. These are dairies producing Grade A milk that is processed for use in products such as fluid milk and yogurt. BOAH currently inspects 34 manufacturing grade plants, which are facilities using manufacturing grade milk as an ingredient in products such as ice cream and cheese. BOAH inspects 13 manufacturing grade farms, which are permitted to supply milk to Indiana's 34 manufacturing grade milk plants. In 2018, Indiana produced 4.15 billion pounds of milk. The state is 14th in the nation for milk production and second in the country for ice cream production.¹ According to 2018 data from the International Dairy Foods Association, more than 19,000 jobs in Indiana are directly tied to the state's dairy industry, contributing 3.2 percent to the state's GDP.²

BOAH has worked to involve regulated entities in the development of the rule. For example, proposed rule changes of the BOAH are presented at the BOAH dairy industry meeting and the annual Indiana Milk Quality Conference. Prior to the first reading of a rule, BOAH sends out emails to interested stakeholders so they are aware of upcoming rulemaking matters before the board. The BOAH posts the board agenda in a prominent location on the website so the rule information can be found on this page in addition to the rulemaking docket. The BOAH also sends out an issues newsletter to stakeholders on a quarterly basis. The affected industry includes small businesses under the definition at [IC 4-22-2.1-4](#).

2. Estimated Annual Reporting, Record Keeping, and Other Administrative Costs

The proposed rule does not increase annual reporting, record keeping, or other administrative costs for regulated entities. As described above, the FSMA requirements were already put in place for manufacturing grade plants in 2016 (LSA Document #16-222). The proposed rule will supplement the FSMA standards currently in the rule with certain sections of the Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO) and frozen dessert sampling standards.

Although the proposed rule will incorporate by reference certain sections of the PMO, this merely provides clarity regarding the specific standards to meet the overarching FSMA standards that are already in effect. In addition, manufacturing grade plants are already adhering to PMO standards in order to move products to customers in other states. It is also important to note that the ice cream sampling standards that are being added are a longstanding practice of the industry and will not involve changes to plant sampling protocols.

3. Estimated Total Annual Economic Impact on Small Businesses

A primary purpose of the proposed rule is to update existing dairy product rules to align with federal standards for Grade A products, which are regulated by the FDA under the PMO. The rule also updates the incorporation by reference of certain FDA food standards that also apply to manufacturing grade milk products, such as cheese and ice cream. Because there have not been significant changes to operational requirements since the last incorporation by reference, BOAH estimates that the total estimated impact (cost) will be less than

\$500,000.

Supplementing the FSMA standards with certain sections of the PMO for manufacturing grade plants will align Indiana with other large dairy states. In addition, this is a favored approach over each state creating its own manufacturing grade standards. BOAH began this transition in 2016 when the state's manufacturing grade standards were repealed and the FSMA standards were phased in (LSA Document #16-222). This rulemaking will complete this transition by referencing appropriate sections of the PMO, which are nationally recognized as the standards that integrate the FSMA standards for the processing of milk products.

4. Justification of Requirements

a. Compliance with Federal and State Law

This proposed rule is necessary to comply with a state mandate. State law requires the board to adopt rules that are the same as, or at least as effective in protecting health, as the federal standards for Grade A milk adopted by the National Conference on Interstate Milk Shipments (NCIMS) in accordance with its Memorandum of Understanding (MOU) with the FDA. [IC 15-18-1-14](#). The PMO is the document that is accepted by the FDA as the federal standards for the interstate shipment of milk. Therefore, in order to comply with this statutory mandate, the agency must ensure that the most recent revision of the PMO is being referenced in the state dairy products rule.

The proposed rule is also necessary to comply with a federal mandate. BOAH is a voting member of the NCIMS. As a member of this entity, each state has agreed to enforce the sanitation standards set forth in the PMO. The FDA audits state program implementation by conducting check ratings. The check rating process involves the FDA inspecting all farms and plants in Indiana every six years. If BOAH does not update the incorporation by reference, Indiana would not be able to enforce the most current federal requirements to ship milk in interstate commerce. Therefore, Indiana would be in violation of its agreement with FDA. If the BOAH does not comply with the MOU, it would have negative consequences with regard to economic development. Indiana's 825 Grade A farms and 25 Grade A plants rely on the board to adopt and enforce the most current version of the PMO. If the board does not incorporate the most recent version of the federal standards, it could jeopardize their ability to ship their product in interstate commerce. This could occur due to a plant or farm failing its milk rating survey, which occurs every two years. A failed survey could result in a plant or a Bulk Tank Unit (BTU), which is comprised of several farms, being delisted from the interstate shippers list. A delisting prohibits a plant or BTU from shipping its milk across state lines. Alternatively, this could occur due to Indiana ultimately failing the FDA check rating process, which would jeopardize the ability for all plants and farms to access out of state markets for their products.

b. Justification of Requirements not Mandated by Federal or State Law

The proposed rule does not impose a requirement or cost beyond what is expressly required by federal or state law. The proposed rule supports economic development by ensuring that all entities engaged in the production of graded milk are adhering to nationally accepted food safety standards. When ungraded milk is stored in a permitted bulk tank with graded milk, or is harvested with common equipment used for graded milk without following best management practices, it presents a public health risk because the ungraded milk may introduce pathogens into the graded product.

This rule change does not prohibit a producer from being involved in both markets. It merely clarifies the expectations with regard to protecting the graded milk from contamination. A producer would not have to purchase additional equipment to comply with this proposed rule. For example, a producer can use the same bulk tank and milking equipment, provided that it adheres to certain management practices pertaining to order of use and washing. Amending this language decreases the risk of individuals becoming ill from a milk product produced under a state permit, which would have a negative economic impact on all Indiana dairy producers and processors.

5. Regulatory Flexibility Analysis

It is the position of the BOAH that the proposed rule does not impose requirements above the current standards in place for manufacturing grade plants. BOAH did not consider alternative approaches to incorporating the PMO because there is a strong preference in the industry for consistency across states. Aligning Indiana's manufacturing grade plant standards with other states will ease the regulatory burden on companies that need to move their products across the U.S. and internationally.

¹ United States Department of Agriculture, National Agricultural Statistics Service, 2018 State Agriculture Overview https://www.nass.usda.gov/Quick_Stats/Ag_Overview/stateOverview.php?state=INDIANA

² American Dairy Association Indiana, Inc. <https://winnersdrinkmilk.com/>